

R432. Health, Health Systems Improvement, Licensing.

R432-650. End Stage Renal Disease Facility Rules.

R432-650-1. Legal Authority.

This rule is adopted pursuant to Title 26, Chapter 21.

R432-650-2. Purpose.

The purpose of this rule is to promote the public health and welfare through the establishment and enforcement of licensure standards. This rule sets standards for the operation and maintenance for End Stage Renal Disease (ESRD) facilities in order to provide safe and effective services.

R432-650-3. Definitions.

(1) The definitions in R432-1-3 apply to this rule.

(2) "Interdisciplinary professional team" means a team of qualified professionals who are responsible for creating the Patient Long Term Care Program and Patient Care Plan. The qualifications are described in 42CFR 405.2137(a) and (b), 1997, which is adopted and incorporated by reference.

R432-650-4. Licensure.

License Required. See R432-2 and R432-3.

R432-650-5. Patient Care Services.

Each ESRD facility must comply with the conditions of participation set forth in the Code of Federal Regulations, Title 42, Part 405, Subpart U., 1997, which is adopted and incorporated by reference.

R432-650-6. Personnel Health.

(1) Each ESRD facility shall establish a written health surveillance and evaluation program for facility personnel commensurate with the services offered. The program must include applicable portions of:

(a) The Communicable Disease Rule, R386-702;

(b) Tuberculosis Control Rule, R388-804; and

(c) OSHA guidelines for Bloodborne Pathogens, 29 CFR 1910.1030.

(2) All employees shall undergo a health status examination as prescribed in the health surveillance and evaluation program upon hiring and may not be assigned to patient care duties until they are determined to be able to safely discharge their duties.

(3) Each ESRD facility must test all employees who provide direct patient care for Hepatitis B within the first two weeks of beginning employment.

(4) Employee skin testing by the Mantoux method or other FDA approved in-vitro serologic test and follow up for tuberculosis shall be done in accordance with R388-804, Special Measures for the Control of Tuberculosis.

(a) The licensee shall ensure that all employees are skin-tested for tuberculosis within two weeks of:

(i) initial hiring;

(ii) suspected exposure to a person with active tuberculosis; and

(iii) development of symptoms of tuberculosis.

(b) Skin testing shall be exempted for all employees with known positive reaction to skin tests.

R432-650-7. Required Staffing.

(1) Each patient shall be under the continuing supervision of a physician. A physician shall be available in medical emergency situations through a current telephone call roster readily accessible to the nursing staff.

(2) Physician assistants and advanced practice registered nurses may provide services in ESRD facilities in association with the supervising or consulting nephrologist, and in accordance with state law.

(3) Each ESRD facility shall provide sufficient qualified clinical staff to meet patient care needs. A minimum of two clinical staff personnel, one a registered nurse for supervision of patient clinical care, shall be on duty whenever patients are receiving dialysis services.

(a) A registered nurse may not supervise the clinical care of more than 10 patients if arranged in an open setting, or 12 patients if arranged in three pods of four patients.

(b) A registered nurse may not supervise patient clinical care, or provide unsupervised patient clinical care until the nurse has completed training and demonstrated competency as determined by facility policy.

(c) Dialysis technicians and licensed practical nurses may not be assigned patient clinical care for more than four patients at a time.

(d) Dialysis technicians and licensed practical nurses must complete training and demonstrate competency according to facility policy prior to providing patient care.

(4) Each ESRD facility must orient all employees to specific job requirements and facility policies. The facility shall document initial and on-going employee orientation and training. Patient clinical care staff orientation and training shall include at least the following topics:

- (a) patient rights and responsibilities;
- (b) kidney disease processes;
- (c) hemodialysis process;
- (d) hemodialysis complications;
- (e) dialysis access and management;
- (f) psycho-social implications of dialysis on patient care;
- (g) nutritional requirements;
- (h) universal precautions;
- (i) use of the medical emergency kit;
- (j) use and function of facility equipment;
- (k) emergency procedures;
- (l) AAMI water treatment standards; and
- (m) dialyzer re-use procedures, if offered.

(5) A registered nurse may delegate the following patient care activities to licensed practical nurses or dialysis technicians:

- (a) cannulation of peripheral vascular access;
 - (b) administration of intradermal lidocaine, intravenous heparin and intravenous normal saline; and
 - (c) initiation, monitoring and discontinuation of the dialysis process.
- (6) Each ESRD facility must ensure that all personnel are licensed, certified or registered as required by the Utah Department of Commerce.

R432-650-8. Patient Care Plan.

- (1) Each patient must have a care plan that is developed and implemented by the interdisciplinary team with the patient's consent within one month of beginning treatment.
- (2) Each patient who receives treatment for more than 90 days must have a long-term care program that is developed and implemented by the interdisciplinary team with the patient's participation.

R432-650-9. Emergency Equipment.

- (1) Each ESRD facility must have available on-site a medical emergency kit containing medications, equipment and supplies. The medical director shall determine and approve the contents of the kit.
- (2) Each ESRD facility must have available on-site an emergency supply of oxygen.

R432-650-10. Drug Storage.

- (1) Each ESRD facility shall provide for controlled storage and supervised preparation and use of medications. Medications and food items may be stored in the same refrigerator if safely separated.
- (a) Medications stored at room temperature shall be maintained within 59-80 degrees F (15-30 degrees C).
 - (b) Refrigerated medications shall be maintained within 36-46 degrees F (2-8 degrees C).
 - (c) Medications must be kept in the original container and may not be transferred to other containers.
- (2) If a medication station is provided, the facility shall provide a work counter and hand washing facilities.

R432-650-11. Medical Records.

- (1) Each ESRD facility must store and file medical records to allow for easy staff access.
- (a) Medical records shall be safeguarded from loss, defacement, tampering, fires, and floods.
 - (b) Medical records shall be protected against access by unauthorized individuals.
- (2) The licensee must retain medical records for at least seven years after the last date of patient care. Records of minors shall be retained until the minor reaches the age of majority plus an additional two years. In no case shall the record be retained less than seven years.
- (3) All patient records shall be retained within the facility upon change of ownership.

R432-650-12. Water Quality.

(1) Water used for dialysis purposes shall comply with quality standards established by the Association for the Advancement of Medical Instrumentation (AAMI) as published in "Hemodialysis Systems," second edition, which is adopted and incorporated by reference.

(2) Each ESRD facility that utilizes in-center water systems must have bacteriologic quality analysis performed and documented at least monthly by a laboratory that adheres to AAMI standards.

(3) For home systems, the ESRD facility must conduct bacteriological quality analysis at least monthly using an approved home testing methodology as identified in the patient care plan.

(a) An alternate schedule of testing may be approved by the attending physician.

(b) The alternate schedule shall be specified in the patient care plan.

(4) If reverse osmosis or deionization devices are used for in-center or home systems, the ESRD facility must have chemical quality analysis performed and documented at least once every 12 months by a laboratory that adheres to AAMI standards.

(5) The ESRD facility must maintain and make available for Department review all water quality test results. In the case of home dialysis, test results shall become part of the patient record maintained by the ESRD facility.

R432-650-13. Continuous Quality Improvement Program.

(1) Each ESRD facility must implement a well-defined continuous quality improvement program to monitor and evaluate the quality of patient care services. The program shall be consistent with the scope of services offered and adhere to accepted standards of care associated with the renal dialysis community.

(2) The program shall include a review of patient care records, facility policies and practices to:

(a) identify and assess problems and concerns, or opportunities for improvement of patient care;

(b) implement actions to reduce or eliminate identified problems and concerns, and improve patient care; and

(c) document corrective actions and results.

(3) The administrator shall establish a committee to implement the continuous quality improvement program. The committee shall include the facility administrator or designee, the medical director, the nursing supervisor, and other individuals as identified in the program.

(4) The committee must meet at least quarterly and keep minutes and related records, which shall be available for Department review.

(5) The continuous quality improvement program may include more than one facility in scope only when the facilities are organized under the same governing body and the program

addresses problems, concerns and issues at the individual ESRD facility level.

R432-650-14. Physical Environment.

The following standards apply for new construction and remodeling of ESRD facilities:

(1) R432-4-1 through R432-4-22 is adopted and incorporated by reference.

(2) ESRD Facilities shall comply with NFPA 101 Life Safety Code as adopted by the Legislature in Title 15A-5-207, The State Construction and Fire Codes Act:, Chapter 20 except that an essential electrical system is not required.

(3) The treatment area may be an open area and shall be separate from the administrative and waiting area. Individual treatment areas must contain at least 80 square feet. Each treatment area shall have the capacity for privacy for each patient for treatment related procedures or personal care.

(4) The dialysis treatment area must include a nurses station designed to provide visual observation of the patient treatment area.

(5) There shall be at least one hand washing facility serving no more than eight stations. All hand washing stations shall be convenient to the nurses station and treatment areas.

(6) A separate blood borne infectious isolation patient treatment room shall be provided and shall:

- (a) be fully enclosed;
 - (b) contain a handwash sink;
 - (c) contain windows to permit observation of the patient from the nurse station and other treatment areas;
 - (d) contain space for clean and soiled gowns and supplies;
- and

(e) be dedicated to patients with blood borne diseases and shall not be used by patients without blood borne diseases.

(7) If an airborne infectious isolation room is required to control airborne infection, the airborne infectious isolation room shall have a separate hand washing facility and comply with R386-702, Communicable Disease Rule, and other applicable standards determined in the pre-construction plan review process. The room shall be tightly sealed and all air from the room shall be exhausted. Exhaust air shall be a minimum of 125 cubic feet per minute greater than supply air.

(a) The airborne infectious isolation rooms may be used for patients without airborne communicable disease when not in use as an isolation room.

(8) If the ESRD facility provides home dialysis training, a private treatment room of at least 120 square feet is required for patients who are being trained to use dialysis equipment at home. The room shall contain a counter, hand washing facilities, and a separate drain for fluid disposal.

(9) Each ESRD facility must provide a clean work area that is separate from soiled work areas. If the area is used for preparing patient care items, it must contain a work counter, hand washing facilities, and storage facilities for clean and sterile supplies. If the area is used only for storage and holding as

part of a system for distribution of clean and sterile materials, the work counter and hand washing facilities may be omitted.

(10) Each ESRD facility must provide a soiled work room that contains a hand washing sink, work counter, storage cabinets, waste receptacles and a soiled linen receptacle.

(11) If dialyzers are reused, a reprocessing room is required that is sized and equipped to perform the functions required and to include one-way flow of materials from soiled to clean with provisions for refrigerated temporary storage of dialyzers, a decontamination and cleaning area, sinks processors, computer processors and label printers, a packaging area, and dialyzer storage cabinets.

(12) If a nourishment station for dialysis service is provided, the nourishment station must contain a sink, a work counter, a refrigerator, storage cabinets, and equipment for serving nourishments as required.

(13) Each ESRD facility must have an environmental services closet immediately available to the treatment area. The closet must contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(14) If an equipment maintenance service area is provided, the service area must contain hand washing facilities, a work counter and a storage cabinet.

(15) Each ESRD facility must provide a supply area or supply carts.

(16) Storage space out of the direct line of traffic shall be available for wheelchairs and stretchers, if stretchers are provided.

(17) Each ESRD facility must provide a clean linen storage area commensurate with the needs of the facility. The storage area may be within the clean work area, a separate closet, or distribution system. If a closed cart distribution system is used for clean linen, the cart must be stored out of the path of normal traffic.

(18) Each ESRD facility using central batch delivery system, must provide, either on premises or through written arrangements, individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(19) Each ESRD facility must house water treatment equipment in an enclosed room at a sufficient distance from the patient treatment area to prevent machinery and operational noise from disturbing patients.

(20) Each ESRD facility must provide a patient toilet with hand washing facilities immediately adjacent to the treatment area.

(21) Each ESRD facility must provide lockers, toilets and hand washing facilities for staff.

(22) Each ESRD facility must provide a secure storage area for patients' belongings.

(23) A waiting area with seating accommodations shall be available or accessible to the dialysis unit. A toilet room with hand washing facilities, a drinking fountain, and a telephone for public use shall be available or accessible for use by persons using the waiting room.

(24) Office and clinical work space shall be available for administrative services.

(25) All finishes shall be tight fitting, easily maintained and cleanable, resistant to cleaning chemicals, and detailed to minimize the potential for microbial growth.

(26) The reprocessing room, water treatment room, supply rooms, clean and soiled work rooms, soiled holding rooms shall be lockable and restricted to authorized personnel only.

(27) The reprocessing room, soiled work, holding room, and environmental services closet shall have continuous exhaust ventilation at the rate of not less than 10 air changes per hour and sufficient to generate inward air flow.

(28) Patient and public toilet rooms and exam rooms shall be equipped with an emergency call system. The call system shall require only momentary contact to activate, shall identify the source of the call and shall be cancelable only at the source of the call. The call system in toilet rooms shall be accessible to a collapsed patient lying on the floor. Inclusion of a pull cord will satisfy this requirement.

R432-650-15. Penalties.

Any person who violates any provision of this rule may be subject to the penalties enumerated in 26- 21-11 and R432-3-6 and be punished for violation of a class A misdemeanor as provided in 26-21-16.

KEY: health facilities

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